

WHAT IS CLAIMED IS:

1 1. A method for forming a working space at an anastomotic site in a
2 body lumen having a wall with an outer surface and an inner surface, and an interior
3 lumen, said method comprising:

4 introducing an inflatable barrier through an access penetration in the wall
5 into the interior lumen of the body lumen;

6 positioning a recessible surface of the inflatable barrier against an
7 anastomotic site on the inner surface of the body lumen wall, wherein the anastomotic
8 site is spaced-apart from the access penetration; and

9 inflating the barrier such that the recessible surface isolates a working
10 space within the lumen.

1 2. A method as in claim 1, wherein the barrier is introduced in a
2 deflated condition through the access penetration and thereafter inflated to create the
3 working space.

1 3. A method as in claim 2, wherein the inflatable barrier has an
2 inflated geometry which defines the working space.

1 4. A method as in claim 3, wherein the working space defined by the
2 inflated geometry is concave or an annular groove.

1 5. A method as in claim 1, further comprising engaging a rigid tool
2 against the recessible surface of the inflated barrier to create the working space.

1 6. A method as in claim 1, wherein introducing comprises introducing
2 a catheter having the barrier at a distal end thereof through a needle.

1 7. A method as in claim 1, further comprising cutting a hole through
2 the wall to prepare the anastomotic site.

1 8. A method as in claim 7, wherein the hole is cut before the barrier is
2 inflated.

1 9. A method as in claim 7, wherein the hole is cut after the barrier is
2 inflated.

1 10. A method as in claim 7, further comprising attaching a graft vessel
2 to the anastomotic site.

1 11. A method as in claim 7, wherein cutting the hole comprises use of
2 a cutting die.

1 12. A method as in claim 1, further comprising deflating the barrier
2 .and withdrawing the deflated barrier through the access penetration.

1 13. A method as in claim 1, wherein introducing comprises advancing
2 the barrier with a shaft passing through the access penetration, wherein an end of the shaft
3 attached to the barrier is curved to facilitate locating the recessible surface of the barrier
4 back against the inner wall of the body lumen.

1 14. A method as in claim 1, wherein positioning the recessible surface
2 of the inflatable barrier comprises pulling on a tether to hold the recessible surface of the
3 barrier against the inner surface of the body lumen wall.

1 15. A method as in claim 14, further comprising advancing a cutting
2 die over or adjacent to the tether, wherein the cutting die includes a hole or channel to
3 align the die with the tether as the die is advanced.

1 16. A method as in claim 15, further comprising attaching an end of a
2 graft vessel to the anastomotic site, wherein the tether is disposed between the graft vessel
3 and the hole in the blood vessel wall.

1 17. A method as in claim 14, wherein the tether is at least partly elastic
2 so that it elastically elongates as tension is applied.

1 18. A method as in claim 1, further comprising protecting the
2 recessible surface of the inflatable barrier against accidental needle penetration during
3 suturing.

1 19. A method as in claim 18, wherein protecting comprises locating a
2 needle penetration guard over at least a portion of the concave surface of the inflatable
3 barrier.

1 20. A method as in claim 19, wherein locating the needle guard
2 deforms the inflatable barrier and creates or enlarges the working space.

1 21. A method as in claim 1, wherein introducing and positioning
2 comprise (a) advancing a curved needle into the body lumen through the access
3 penetration and out of the body lumen through the anastomotic site, and (b) pulling on a
4 tether attached to the inflatable barrier to draw the recessible surface of said barrier
5 against the inner surface of the body lumen.

1 22. A method as in claim 21, further comprising introducing a needle
2 penetration guard through the anastomotic site over the recessible surface.

1 23. A method as in claim 22, wherein the needle penetration guard has
2 a shaft which extends through a catheter attached to the inflatable barrier , wherein both
3 the shaft and catheter extend back through the penetration hole.

1 24. A method as in claim 23, further comprising withdrawing the
2 inflatable barrier and the needle penetration guard through the access penetration.

1 25. A method as in claim 24, wherein the needle penetration guard is
2 removed first by withdrawing through a catheter lumen.

1 26. A method as in claim 25, wherein the needle penetration guard
2 unravels as it is withdrawn through the catheter.

1 27. Apparatus for isolating a working space in a blood vessel having a
2 wall with an outer surface, an inner surface, and an interior lumen, said apparatus
3 comprising:

4 an inflatable barrier having a recessible surface which is adapted to
5 conform to and seal against the inner surface of the blood vessel wall to define the
6 working space at an anastomotic site; and

7 means for introducing and deploying the inflatable barrier through a
8 penetration in the blood vessel wall, wherein the penetration is spaced-apart from the
9 anastomotic site.

1 28. Apparatus as in claim 27, wherein the introducing means comprises
2 a catheter having a proximal end, a distal end, and an inflation lumen therethrough,
3 wherein the inflatable barrier is attached at or near the distal end of the catheter.

1 29. Apparatus as in claim 28, wherein at least a distal portion of the
2 catheter is curved and the barrier is oriented so that it can be pushed by the catheter
3 against a location axially spaced-apart from the penetration through which the barrier and
4 catheter were introduced.

1 30. An apparatus as in claim 29, wherein the curved distal portion
2 induces a first radially divergent curve and a second radially convergent curve.

1 31. Apparatus as in claim 30, wherein the introducing means further
2 comprises a tether extending distally from the barrier, wherein said tether is adapted to be
3 passed through the anastomotic site wall to permit tensioning of the barrier by drawing
4 outwardly on the tether.

1 32. Apparatus as in claim 30, further comprising a curved needle
2 attached to a distal end of the tether, wherein the curve of the needle is "similar or
3 congruent" with the first curve of the catheter.

1 33. Apparatus as in claim 32, wherein at least one of the needle and the
2 catheter is at least partly malleable so that it can be shaped prior to use.

1 34. Apparatus as in claim 26, wherein the inflatable barrier comprises
2 an elastomeric balloon.

1 35. Apparatus as in claim 35, wherein the balloon has a torroidal
2 geometry.

1 36. Apparatus as in claim 34, wherein the recessible surface comprises
2 an annular groove to define the working space.

1 37. Apparatus as in claim 34, wherein the recessible balloon surface
2 comprises a flat or convex surface which can be engaged by a rigid tool to define the
3 working space.

1 38. Apparatus as in claim 35, further comprising a needle penetration
2 shield.

1 39. Apparatus as in claim 38, wherein the needle penetration shield
2 comprises a layer of a puncture-resistant material laminated to the balloon surface.

1 40. Apparatus as in claim 38, wherein the needle penetration shield is a
2 separate tool that can be introduced through the anastomotic site.

1 41. Apparatus for isolating a working space in a body lumen having a
2 wall, an inner surface, and an interior lumen, said apparatus comprising:
3 an inflatable barrier structure having a recessible surface which is adapted
4 to conform to and seal against the inner surface of the body lumen wall to define the
5 working space; and
6 a needle penetration guard engageable against the recessible surface of the
7 inflatable barrier when the barrier is inflated.

1 42. Apparatus as in claim 41, wherein the inflatable barrier structure
2 comprises a catheter having a proximal end, a distal end, and an inflation lumen
3 therethrough; wherein the inflatable barrier is attached at or near the distal end of the
4 catheter.

1 43. Apparatus as in claim 42, wherein the catheter has at least an
2 inflation lumen and a shaft-receiving lumen extending therethrough.

1 44. Apparatus as in claim 43, wherein the needle penetration guard
2 comprises a shield surface and a shaft attached to the shield surface, wherein the shaft is
3 adapted to pass into and through the shaft-receiving lumen of the inflatable barrier
4 catheter when the shield is in place over the recessible surface.

1 45. Apparatus as in claim 44, wherein the needle penetration guard
2 further comprises a removable placement tool which detachably couples to the shield
3 surface on a side opposite to the shaft.

1 46. Apparatus as in claim 42, wherein the at least a distal portion of the
2 catheter is curved and the barrier is oriented so that it can be pushed by the catheter

3 against a location axially spaced-apart from the penetration through which the barrier and
4 shaft were introduced.

1 47. Apparatus as in claim 46, wherein the curved distal portion induces
2 a first radially divergent curve and a second radially convergent curve.

1 48. Apparatus as in claim 47, further comprising a tether extending
2 distally of the inflatable barrier to permit tensioning of the barrier by drawing outwardly
3 on the tether.

1 49. Apparatus as in claim 48, further comprising a curved needle
2 attached to the tether.

1 50. Apparatus as in claim 49, wherein the curve of the needle is
2 "similar or congruent" with the curve of the distal end of the catheter.

1 51. Apparatus as in claim 49, wherein the needle and the catheter are
2 malleable so that the curves can be changed.

1 52. A method as in claim 15, further comprising attaching an end of a
2 graft vessel to the anastomotic site, wherein the tether is disposed through the hole in the
3 blood vessel and outside of a lumen of the graft vessel.

1 53. A method as in claim 24, wherein the needle penetration guard is
2 removed by withdrawing through the anastomotic site.

1 54. A method as in claim 44, wherein the needle penetration guard is
2 adapted to uncoil when withdrawn from the vessel.